UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
STATE OF CALIFORNIA,
STATE OF DELAWARE,
STATE OF FLORIDA,
STATE OF GEORGIA,
STATE OF HAWAII,
STATE OF ILLINOIS,
STATE OF INDIANA,
STATE OF LOUISIANA,
STATE OF MASSACHUSETTS,
STATE OF MICHIGAN,
STATE OF NEVADA,
STATE OF NEW HAMPSHIRE,
STATE OF NEW JERSEY,
STATE OF NEW MEXICO,
STATE OF NEW YORK,
STATE OF OKLAHOMA,
STATE OF RHODE ISLAND,
STATE OF TENNESSEE,
STATE OF TEXAS,
STATE OF WISCONSIN,
COMMONWEALTH OF VIRGINIA, and
DISTRICT OF COLUMBIA,

EX REL. JOSEPH PIACENTILE,
Plaintiffs,

vs.

SANOFI SYNTHELABO, INC. and AVENTIS PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 05-cv-2927 (KSH)(PS)

JURY TRIAL DEMANDED

AMENDED COMPLAINT

Relator Joseph Piacentile, M.D. ("Relator" or "Dr. Piacentile"), on behalf of the United States of America and on behalf of the sovereign states of California, Delaware, Florida,

Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin and the Commonwealth of Virginia and the District of Columbia (the "Certain States"), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729-3733 (2004) (the "FCA"), and the false claims acts of the Certain States (the "state false claims acts"), files this Amended Complaint against Defendants Sanofi Synthelabo, Inc. ("Sanofi") and Aventis Pharmaceuticals, Inc. ("Aventis") (collectively, "Defendants") and alleges as follows:

INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America and the Certain States, arising from false or fraudulent claims for reimbursements submitted or caused to be submitted or by failing to provide the Best Price by Sanofi and Aventis to federal government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits Program ("FEHBP") and TRICARE/CHAMPUS, for prescription drugs, in violation of the FCA and the state false claims acts. The FCA specifically prohibits the Defendants' conduct involving kickbacks and price discounts, and causing the submission of non-reimbursable claims to Medicaid and other government-funded health programs.

2. The state false claims acts are modeled after the FCA and seek to prevent similar harms to state treasuries. *See* the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Delaware False Claims Act, Del. Code. Ann. tit. 6, §§ 1201, *et seq.* (2004); the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081, *et seq.* (2004); the Georgia False Medicaid Claims Act, Ga. Code. Ann. §§ 49-4-168.1 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-22, *et seq*. (2004); the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§ 175/1, *et seq.* (2004); the Indiana False Claims and Whistleblower Protection Act, Ind. Code

§§ 5-11-5.5-1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:439.1, *et seq.* (2004); the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(O) (2004); the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 , *et seq.* (2004); the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61, *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1, *et seq.* (2004); the New York False Claims Act, N.Y. Fin. Law §§ 187, *et seq.* (2007); the Oklahoma Medicaid False Claims Act, 63 Okla. St. Ann. §§ 5053 *et seq.*; The State False Claims Act (Rhode Island), R.I. Gen. Laws §§ 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181, *et seq.* (2004), and the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101, *et seq.* (2004); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.001, *et seq.* (2004); the Wisconsin False Claims for Medical Assistance Law, Wisc. Stat. § 20.931; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1, *et seq.* (2004); and the District of Columbia False Claims Act, D.C. Code §§ 2-308.03, *et seq.* (2004).

3. Defendants have violated and continue to violate federal anti-kickback and related statutes, as well as corresponding provisions of the state false claims acts, by routinely paying kickbacks to physicians in order to induce those physicians to prescribe approved and non-approved uses of Sanofi and Aventis prescription drugs, including Taxotere (generic name docetaxel), Anzemet (generic name dolasetron), Plavix (generic name clopidogrel bisulfate) and Avapro (generic name ibersartan), and to induce physicians to recommend those same drugs to their fellow physicians.

4. The illegal kickbacks paid by the Defendants come in many forms, including free drug samples for which the physician or medical institution bills the government at full cost, cash payments, sham "research grants," and other benefits to high-prescribing physicians who attend lavish meetings. By paying illegal kickbacks to physicians which are not disclosed to the government in violation of 42 U.S.C. § 1320a-7b(b) (the "Medicare Fraud & Abuse/Anti-Kickback Statute"), the Defendants caused false or fraudulent claims to be filed by physicians and medical institutions for reimbursement for Sanofi and Aventis drugs from federal government-funded health programs. The Defendants' conduct, as such, violated the FCA and the state false claims acts.

5. By paying illegal kickbacks and offering price discounts to physicians which are not disclosed to the government in violation of 42 U.S.C. § 1396r-8 (the "Medicaid Rebate Statute"), Sanofi and Aventis caused and/or induced physicians and medical institutions seeking reimbursement for Sanofi and Aventis drugs from federal government-funded health programs to file false or fraudulent certifications in violation of the FCA and the state false claims acts.

6. Aventis further waged an illegal "off-label" marketing campaign to promote its prescription drug Taxotere for uses unapproved by the United States Food and Drug Administration ("FDA").[1] Rather than awaiting FDA approval for the drug's alternate uses, Aventis chose to promote off-label uses of Taxotere despite its awareness of the FDA's prohibition on off-label marketing. Aventis's off-label marketing scheme caused physicians and medical institutions to submit and receive payment for false or fraudulent claims in violation of the FCA, causing government-funded health programs, in turn, to pay reimbursements that otherwise would not have been paid. Moreover, Aventis's off-label marketing scheme corrupted

[1] The FDA reviews a pharmaceutical manufacturer's application for approval of a new drug to determine whether the drug's intended use is safe and effective. 21 U.S.C. § 355. "Off-label" use refers to prescriptions of a drug for a *use* that has not been approved by the FDA.

the independent medical judgment of physicians and risked patients' health by improperly influencing physicians' decisions whether to prescribe Taxotere and whether to disclose its harmful side effects to patients.

7. The Defendants' schemes illegally increased the market share for their products by inducing physicians to prescribe medications they would not otherwise have prescribed but for the receipt of the kickbacks and/or other illegal marketing efforts. The Defendants' unlawful kickback schemes caused false, fraudulent and improper billings to be made to Medicare, Medicaid, and other government-funded health programs. The federal government and the Certain States consequently paid enormous sums for reimbursement claims they would have rejected had they been aware of the Defendants' illegal actions. Moreover, as a result of the Defendants' illegal promotions, the public overutilized Sanofi and Aventis drugs, prescription drug costs to the federal government and the certain states soared, and, in turn, the Defendants reaped illegal profits.

8. Because of the Defendants' unlawful promotion schemes, patients receiving Sanofi and Aventis prescription drugs for unapproved and unproven uses received no assurance that their doctors were exercising their independent and fully-informed medical judgment.

9. The Defendants have engaged in their wrongful conduct since they first introduced Taxotere, Anzemet, Plavix and Avapro to the market. The Defendants' wrongful conduct has continued through to the present.

10. The Defendants concealed their unlawful conduct by, among other actions, never disclosing that they were engaged in illegal off-label marketing and the payment of kickbacks to physicians.

11. By this action, Relator seeks to recover on behalf of the United States of America and the Certain States damages and civil penalties arising from the false or fraudulent claims that the Defendants submitted or caused to be submitted to government health programs.

I. JURISDICTION AND VENUE

12. Relator brings this action on behalf of himself and on behalf of the United States of America for violations of the FCA, 31 U.S.C. §§ 3729-3733 and on behalf of the Certain States for violations of the state false claims acts. *See also* The Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*; The Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. §§ 351 *et seq.* and 21 U.S.C. §§ 360aaa *et seq.*; the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. §§ 1320a *et seq.*; and the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8.

13. This Court has jurisdiction over the subject matter of this action pursuant to § 28 U.S.C. § 1331, and 31 U.S.C. § 3732(a), which specifically confers this Court with jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the state false claims acts pursuant to 31 U.S.C. § 3732(b), as well as supplemental jurisdiction over the counts relating to the state false claims acts pursuant to 28 U.S.C. § 1367.

14. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in the State of New Jersey within this judicial district. Section 3732(a) authorizes nationwide service of process. *Id.*

15. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this District.

16. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint has been filed under seal and will remain under seal for a period of at least 60 days from its filing date, and shall not be served upon the Defendants until the Court so orders.

17. Pursuant to 31 U.S.C. § 3730(b)(2), Relator must provide the government with a written disclosure of substantially all material evidence and material information in his possession contemporaneous with the filing of the Complaint. Relator has complied with this provision by serving copies of this Complaint on Christopher J. Christie, United States Attorney for the District of New Jersey, and Michael B. Mukasey, United States Attorney General.

18. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A).

19. To the extent that there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relator, Relator is an original source of this information as defined in 31 U.S.C. § 3730(e)(4)(B). Relator possesses direct and independent knowledge of the information, which he acquired in the course of conducting an undercover investigation of Sanofi and Aventis. Relator voluntarily provided the government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

II. PARTIES

20. Relator, Joseph Piacentile, M.D., resides in the state of New Jersey and is a licensed, non-practicing physician currently engaged as a consultant to an e-prescribing company. Relator has direct and independent personal knowledge of the Defendants' practices as a result of an extensive independent investigation he personally conducted into Sanofi and

Aventis's wrongdoing during which he secured admissions from key marketing executives of Sanofi and Aventis regarding the allegations set forth herein. Relator brings this action for violations of the FCA on behalf of himself and the United States of America, and on behalf of the Certain States for violations of the state false claims acts.

21. Defendant Aventis Pharmaceuticals, Inc. is a corporation incorporated in Delaware, headquartered at 300 Somerset Corporate Blvd., Bridgewater, New Jersey 08807-2854, and is a U.S. affiliate of the Sanofi-Aventis Group SA. On October 13, 2004, Sanofi Synthelabo SA, headquartered in Paris, France, along with its U.S. affiliate Sanofi Synthelabo, Inc. ("Sanofi"), incorporated in Delaware and headquartered in New York, New York, merged operations with Aventis SA, headquartered in Strasbourg, France, as part of the newly-formed Sanofi-Aventis Group SA. Until that merger, the Bridgewater offices served as the U.S. headquarters of Aventis SA. Following the merger, the Sanofi-Aventis Group SA became the third largest drug company in the world.

22. Aventis is engaged in the business of manufacturing, marketing and selling prescription drugs throughout the United States of America. Among its many products, Aventis manufactures and markets the oncology drug Taxotere, the antiemetic drug Anzemet and various leading vaccines. In 2003, Aventis generated revenues of approximately $7.21 billion in the U.S., due in part to the robust sales of Taxotere and Anzemet.

23. Sanofi Synthelabo, Inc. is incorporated in Delaware and headquartered at 90 Park Avenue, New York, N.Y. 10016. On October 13, 2004, Sanofi Synthelabo merged with Aventis SA to become the Sanofi Aventis Group, S.A., headquartered in Paris, France.

24. Sanofi is engaged in the business of manufacturing, marketing and selling prescription drugs throughout the United States of America. Sanofi, the seventh large drug

manufacturer in the U.S., produces the anti-clotting medication Plavix, the cardiovascular drug Avapro and the rectal cancer drug Eloxatin, among other leading drugs. In 2002, Sanofi sold more than $4.5 billion in drugs in the U.S., in part because Plavix sales increased 40 percent.[2]

25. The federal and state governments, through their Medicaid and Medicare programs, are among the principal purchasers of Sanofi and Aventis products.

III. BACKGROUND

A. The False Claims Act

26. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the government's ability to recover losses sustained as a result of fraud against the United States.

27. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1),(2). The Act empowers private persons having information regarding a false or fraudulent claim against the government to bring an action on behalf of the government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the government conducts an investigation of the allegations in the complaint and determines whether to join the action. *Id.*

28. Payment of kickbacks or undisclosed price discounts to physicians to induce them to prescribe a reimbursable drug, and promotion of off-label uses of such drugs, by a person who

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[2] Bristol-Meyers Squibb Company ("BMS") is a pharmaceutical manufacturer, organized and existing under the laws of the state of Delaware. According to BMS's 2004 10-K, Sanofi drugs Plavix and Avapro were jointly developed and marketed pursuant to a joint venture between BMS and Sanofi.

seeks reimbursement from a federal government health program for the drug, or who causes another to do so, while certifying or impliedly certifying compliance with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute and the Food, Drug and Cosmetics Act, or while causing another to do so, constitutes a violation of the FCA.

B. Federal Government Health Programs

29. Medicare is a federal government health program primarily benefiting the elderly that Congress created in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare will not pay for over-the-counter drugs or most self-administered prescription drugs until the Medicare Prescription Drug Improvement and Modernization Act of 2003 is fully implemented. Under certain conditions, however, Medicare Part B covers drugs used in association with chemotherapy treatments such as Taxotere and Anzemet, and with hypertension treatments, such as Plavix and Avapro.

30. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the federal government and those state governments choosing to participate in the program. The federal government also separately matches certain state expenses incurred administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than Medicare.

31. Medicaid coverage for prescription drugs is significantly more expansive than that provided by Medicare. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.

32. TRICARE is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

33. The FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

C. FDA Regulation of Pharmaceuticals

34. Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301, *et seq.*, the FDA strictly regulates, among other things, the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies in promoting and selling FDA-approved prescription drugs.

35. The FDA regulates drugs based on the "intended uses" for such products. A manufacturer who wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. §§ 331(d), 355(a) and 360b(a).

36. The FDA reviews a pharmaceutical manufacturer's application for approval of a new drug to determine whether the drug's intended use is safe and effective. *See* 21 U.S.C. § 355. "Off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA scrutiny and approval.

37. Once a drug is approved for a particular use, the FDA allows doctors to prescribe the drug for medical uses that are different from those approved by the FDA. The FDA also allows doctors to request information from drug manufacturers about off-label uses of FDA-approved drugs. However, with very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved.

38. Any failure to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. *See* 21 U.S.C. §§ 331(a)-(b), 352(a),(f),(n).

39. Any presentations, promotions, or marketing to physicians for products for use other than that approved for labeling purposes by the FDA is considered off-label marketing and is prohibited by the FDA. *See* 21 U.S.C. §§ 331(a)-(b), 352(a),(f).

D. The Medicare Fraud & Abuse/Anti-Kickback Statute

40. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years.

41. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals, or that takes into account the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). Such remuneration amounts to a kickback when it is paid to induce or reward the drug prescriptions written by physicians. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Such kickbacks also reduce a patient's healthcare choices as unscrupulous or unknowing physicians steer their patients to various drug products based on the physician's own financial interests rather than the patient's medical needs.

42. The Medicare Anti-Kickback Statute contains eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7(b)(3). None of the statutory exceptions or regulatory safe harbors protects the Defendants' conduct in this case.

43. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Act to include an administrative civil money penalty provision for violating the Medicare Anti-Kickback Statute. The administrative sanction is $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such

remuneration was offered, paid, solicited, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

E. The Medicaid Rebate Statute

44. The Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, is designed to return money to the Medicaid program in the form of rebates from drug manufacturers. Federal law provides that drug manufacturers must pay rebates to the states to ensure that the Medicaid program is paying the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser in the United States, inclusive of cash discounts, free goods, kickbacks, volume discounts, and rebates. The "best price" provision is intended to ensure that the government is being provided the lowest price on drugs.

45. To have their drugs eligible for Medicaid payment, all drug manufacturers must provide "best price" information to CMS. CMS uses this "best price" information to calculate rebates payable to the Medicaid program.

46. Drug manufacturers provide both "best price" information and Average Manufacturer Price information to CMS. CMS then calculates a unit rebate amount, and provides that information to state Medicaid agencies. The states then consider utilization data provided by pharmacies, and the unit rebate amount, to calculate the rebate owed to them by the manufacturer. The entire system, however, is based upon manufacturers honestly conveying to CMS correct "best price" information and Average Manufacturer Price ("AMP") information. Any overstatement of the best price, intentional or unintentional, will cause an underpayment in rebate amounts.

47. The Medicaid Rebate Statute states, in part, that the term "best price" shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume

discounts, and rebates (other than rebates under this section). *See* 42 U.S.C. § 1396r-8(c)(1)(c)(ii).

48. The federal government has great financial interest in the program. The Medicaid Rebate Statute provides that amounts received by the states under the "best prices" program "shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of" calculating the federal contribution to state Medicaid programs. *See* 42 U.S.C. § 1396r-8(b)(1)(B).

49. As a result of pervasive "best price" fraud, the Office of Inspector General promulgated compliance materials on May 5, 2003 which observed that manufacturers have "a strong financial incentive to hide *de facto* pricing concessions" (in particular, kickbacks and price discounts) that could affect "best price" calculations and trigger increased Medicaid rebates. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FEDERAL REGISTER 23731, 23735 (May 5, 2003). Moreover, the Office of Inspector General instructed manufacturers to report "best prices" which "accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." *Id.* at 23733-23734. In sum, according to the Office of Inspector General, "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes." *Id.*

50. The Medicaid program reimburses doctors only for "covered outpatient drugs" for which a rebate is paid by the drug's manufacturer. 42 U.S.C. § 1396b(i)(10). Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not

issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). A "medically accepted indication" includes only those indications approved by the FDA, and those "off-label" uses that are "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6).[3]

IV. SUBSTANTIVE ALLEGATIONS

A. Aventis Prescription Drugs Taxotere and Anzemet; Sanofi Drugs Plavix and Avapro

51. Docetaxel, an antineoplastic cancer drug manufactured and marketed by Aventis under the brand name "Taxotere," is principally used to treat metastatic or advanced breast cancer. Prior to May 2004, the FDA had approved Taxotere only for the treatment of locally advanced or metastatic breast cancer after failure of prior chemotherapy, and for locally-advanced or metastatic non-small cell lung cancer, under certain conditions. Until May 2004, Aventis was prohibited from marketing and promoting Taxotere for treatment of prostate cancer. Until August 2004, Aventis was prohibited from marketing and promoting Taxotere for treatment of forms of breast cancer other than locally advanced or metastatic breast cancer.

52. On May 19, 2004, the FDA approved the use of Taxotere, in conjunction with prednisone (a steroid), for the treatment of advanced stage or metastatic prostate cancer, adding to the drug's previously approved uses for treatment of advanced states of breast cancer and lung cancer. On August 19, 2004, the FDA approved the use of Taxotere, in combination with doxorubicin and cyclophosphamide, for adjuvant (post-surgery) treatment of patients with operable, node-positive, early stage breast cancer. Since that time, the FDA has not approved the drug for any new, alternative uses.

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[3] Similarly, Medicare will cover the off-label use for a prescription drug only if that off-label use is properly supported by a major medical compendium and is approved for such use by the Centers for Medicare and Medicaid Services. *See* Section 1861(t)(1) of the Social Security Act, 42 U.S.C. § 1395x.

53. Dolasetron, an antiemetic cancer drug manufactured and marketed by Aventis under the brand name "Anzemet," is used to control nausea and vomiting caused by chemotherapy treatment. The FDA has approved Anzemet for treatment of nausea and vomiting associated with emetogenic cancer chemotherapy and for the treatment of post-operative nausea and/or vomiting.

54. Clopidogrel bisulfate, an antiplatelet drug manufactured and marketed under the brand name "Plavix," is used to reduce the risk of heart attack, stroke, or vascular death associated with arterial disease. Plavix is manufactured and marketed in the U.S. by Sanofi. The FDA has approved Plavix for use in patients with a history of recent heart attack, recent stroke, or established peripheral arterial disease (poor circulation in the legs which may cause pain), as well as in patients with acute coronary syndrome.

55. Ibersartan, an antihypertensive agent used to treat hypertension, is marketed under the brand name "Avapro." Avapro is manufactured and marketed in the U.S. by Sanofi. The FDA has approved Avapro for treatment of certain forms of nephropathy in patients with type 2 diabetes and hypertension.

56. By paying kickbacks to physicians to induce them to prescribe Taxotere, Anzemet, Plavix and Avapro, and by promoting off-label uses of Taxotere, Sanofi and Aventis violated a series of applicable statutes and regulations, including, without limitation, the Medicare Anti-Kickback Statute, the Medicaid Rebate Statute, the FDCA and the FCA. In violating these statutes, Aventis and Sanofi encouraged doctors to overutilize potentially inappropriate, risky or unnecessary prescription drugs, induced excessive payments from federal government health programs, and thereby reaped improper profit through their illegal inducements. Further, Aventis corrupted the independent medical judgment of physicians and

risked patients' health by improperly influencing physician's decisions whether to prescribe Taxotere and whether to disclose its harmful side effects to patients.

B. Aventis's Unlawful Off-Label Marketing Scheme

57. During relevant periods, Aventis's efforts to market Taxotere off-label were intended to increase Aventis's sales of the drug, and violated the FDCA and other FDA regulations that prohibit off-label marketing.

58. While aware of the illegality of marketing prescription drugs for non-FDA-approved uses, Aventis knowingly marketed Taxotere for such off-label, unapproved purposes as prostate cancer (before it was approved in May 2004), and early stage breast cancer (before a limited use was approved in August 2004), from as early as 1996. Specifically, prior to the FDA's approval of Taxotere for treatment of prostate cancer and operable node-positive, early stage breast cancer, Aventis sponsored purportedly educational conferences discussing these off-label uses, for which physicians would receive Continuing Medical Education ("CME") credit.

59. Aventis's sponsorship of CME and other conferences regarding prostate cancer and early-stage breast cancer constituted improper off-label marketing because, irrespective of whether physicians had prescribed Taxotere off-label for treatment of these conditions, the activities of Aventis sales professionals regarding the conferences were in substantial part promotional rather than educational in nature. For example, prior to the arrangement of one of these conferences, a marketing representative asked Aventis's sales force for a list of "heavy hitters," *i.e.*, high-prescribing physicians, to invite to the event.

60. In the course of his investigation, Relator learned that Aventis marketed Taxotere for prostate cancer well before the FDA approved such a use. Likewise, Aventis marketed Taxotere for early-stage breast cancer long before that use was approved by the FDA. Further, on information and belief, Aventis marketed Taxotere for other non-FDA-approved uses during

relevant periods, and has continued such conduct through to the present. Furthermore, upon information and belief, Aventis has engaged in the illegal marketing and promotion of Taxotere on a nationwide basis, resulting in a substantial quantity of off-label prescriptions for Taxotere.

61. Relator learned of specific examples of Aventis's illegal off-label marketing campaign through his investigation, and in particular through conversations with former Aventis employees Mark Campbell and Rohan Ramharack. Mr. Campbell and Mr. Ramharack were responsible for marketing the Company's products to physicians in the New York and New Jersey area under the direction of Aventis management. Relator's conversations with these individuals took place from November 7, 2003 to May 23, 2004.

62. Through these conversations, Relator learned that Aventis had regularly engaged in the illegal practice of off-label marketing. To carry out this unlawful practice, Aventis employed and continues to employ approximately 30 regional "Professional Oncology Education Managers" ("POEMs"), who exist solely to promote the prescription of Aventis drugs for off-label uses through conferences, conventions, and other promotional efforts. POEMs usually consist of former physicians or nurses who lend their credibility and expertise to the promotion of Aventis drugs. Each POEM assembles lists of physicians who are likely to prescribe Taxotere for off-label uses, and pays those physicians to attend speaker events, such as Taxotere Advisory Board symposia, for which they are also typically eligible to receive CME credit.

63. Although the advertised purpose of these events is strictly educational and non-promotional, the role of POEMs at these events is blatantly commercial in nature. In addition to paying physicians both to speak at and to attend these promotional events, Aventis also illegally assists the speakers in presenting materials on off-label uses for Taxotere. Mr. Campbell explained that Aventis assigns one POEM to each of the Company's regional sales districts, and

that all of them are involved in similar work with respect to off-label marketing. Relator thus learned that Aventis engages in a nationwide illegal off-label marketing campaign.

64. Aventis enlisted POEMs to wage aggressive campaigns to market their products for targeted non-FDA approved purposes, one of which Mr. Campbell identified on May 25, 2004 as early stage breast cancer, a use for which Taxotere was not FDA-approved until August 2004. Once the FDA approves an Aventis drug for a previously off-label purpose, the POEMs' work on that particular product is concluded, and they then move on to a new project or "program."

65. Relator learned from Mr. Campbell that members of Aventis's sales force were engaged in, and continue to be engaged in, efforts to persuade doctors to use Taxotere "in more tumor types" other than its limited FDA-approved uses.

66. Aventis engaged in a marketing campaign to promote off-label prescriptions for its drugs, in violation of the FDCA, FDA regulations, the FCA and the state false claims acts. In doing so, Aventis caused physicians and other healthcare providers to submit claims for reimbursement to government-funded health insurers for drugs that the government would not have paid had it known the truth about the Aventis's illegal off-label marketing efforts.

67. Upon information and belief, Aventis actively concealed its off-label marketing to preserve the flow of federal and state funds to reimburse prescription claims for its drugs that were improperly submitted due to the off-label marketing of Aventis drugs.

(1) Non-Reimbursable Claims

68. Federal Medicaid regulations prohibit the payment of Medicaid claims for prescriptions for many off-label uses of pharmaceutical drug products. *See also* 42 U.S.C. § 1395(a)(1), (g)(1).

69. Aventis's aggressive marketing of the off-label uses of Taxotere to treat prostate cancer and early stage breast cancer caused prescriptions for Taxotere to be written based upon that off-label marketing, and consequently caused false claims to be submitted to Medicaid and other government health programs.

70. Prescriptions written for Taxotere and paid for by Medicaid and other government health programs due to Aventis's aggressive off-label marketing of Taxotere constitute false claims. Had the government known of Aventis's illegal off-label marketing campaign, it would not have reimbursed prescriptions written for the illegally promoted drugs.

71. Both the Medicare and Medicaid programs include detailed statutory and regulatory provisions concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full federal and state participation, price controls on prescription drugs, and drug manufacturer rebate agreements.

72. The government would not have reimbursed physicians and medical institutions for off-label use of Aventis drugs if it had known the truth about Aventis's illegal marketing scheme, as Aventis knew or should have known.

73. In determining whether to reimburse physicians and medical institutions for prescription drugs, government-funded health programs rely upon physicians and medical institutions to provide them with information regarding the uses for which the drugs were prescribed.

74. Because Aventis knew that physicians and medical institutions would seek reimbursement from the government for off-label prescriptions of Aventis drugs, and would do so without disclosing Aventis's illegal promotion of those off-label uses, Aventis caused

physicians and medical institutions to submit false or fraudulent claims for reimbursement to the government.

75. On every occasion in which a physician or medical institution requested reimbursement from government-funded health programs for an Aventis drug that was prescribed for an unauthorized, off-label use that Aventis had illegally promoted or marketed, Aventis caused a false or fraudulent claim to be submitted.

76. On every occasion in which a physician or medical institution submitted a false claim by billing for medicine prescribed for an unauthorized, off-label use that Aventis illegally promoted or marketed, Aventis knew or acted in reckless disregard of the fact that a false claim would be submitted, and is itself liable for the false claim.

77. In addition, because Aventis knew or had reason to know that several of its drugs were being prescribed for non-approved uses (pursuant to its illegal marketing), it was obligated by law to provide adequate labeling for its drugs to cover such unapproved uses. Upon information and belief, it did not do so.

C. Aventis's Unlawful Kickback Scheme

78. Aventis routinely pays kickbacks and other illegal remuneration to physicians to induce them to prescribe Aventis drugs, including Taxotere and Anzemet, to increase Aventis's prescription drug market share and ultimately its profits. The kickbacks Aventis pays to prescribing physicians come in many forms, including cash payments, sham "research grants," free services, free equipment, drug price discounts, free samples and overfilling of prescriptions, and other inducements. By paying illegal kickbacks and offering price discounts to physicians which are not disclosed to the government in violation of 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute), Aventis has caused and/or induced physicians and medical institutions which sought reimbursement for Aventis drugs from federal government-funded health programs to file

false or fraudulent certifications regarding compliance with the foregoing statutes in violation of the FCA and the state false claims acts.

79. Further, Aventis targeted many kickbacks to those prominent physicians and other healthcare professionals whose stature enabled them to influence their institutions' drug purchasing decisions.

80. On every occasion in which a physician or medical institution received a kickback or price discount from Aventis and later sought reimbursement for Aventis drugs from federal government-funded health programs, a false claim was submitted in violation of the FCA.

81. Relator's investigation uncovered specific and substantial evidence of Aventis's payment of kickbacks to physicians to increase market share.

1. Kickbacks to Induce Sales

82. Aventis routinely pays kickbacks and other rewards to physicians to illegally influence physicians to prescribe its prescription drugs, including Taxotere and Anzemet, to increase its share of the prescription drug market.

83. The kickbacks Aventis pays to prescribing physicians come in many forms, including free drugs that were then charged to the government as if the doctor or medical institution had paid for them, cash payments, so-called research grants, free services, overfilled prescriptions and other inducements.

84. Relator learned through his conversations with sales representatives that Aventis provides its sales representatives with budgets of as much as $36,000 to use at their discretion to induce physicians to prescribe the Company's drugs or to reward physicians for large purchases. Part of this discretionary budget is referred to as a "martini budget" to be spent on "customers" who show "potential" for giving more business, *i.e.*, for prescribing more Aventis drugs.

85. Aventis also provides marketing funds to be used as "speaker fees" to reward four or five physicians a year who are high volume customers. High volume customers are identified through examination of data from IMS Health, Inc., a service that tracks doctor prescriptions. The sales representative proposes the doctor's bonus to his manager, and the Aventis manager then "co-sponsors" the payment. The sponsored physicians are then paid about $2,000 to $3,000 or more, to attend lavish dinners at which they speak to other physicians about Aventis drugs.

86. The Relator also learned through Mr. Campbell that Aventis tailors its grants to physicians as rewards for purchasing its drugs, rather than as funding for legitimate research purposes. In addition, these grants were initiated and directed by Aventis's sales and marketing agents rather than its science division.

87. For example, such "educational" grants were provided to Dr. Clifford Huddis, chief of breast cancer medicine service at Sloan Kettering Cancer Center in New York, to induce him to promote Taxotere at his hospital. Indeed, Dr. Huddis played a central role in boosting Sloan Kettering's purchases of Taxotere from 170 vials a month to as many as 400 vials a month, mostly for off-label use.

88. Nadir Rizby at Sloan Kettering Cancer Center and Michael Kane, of the Cancer Institute of New Jersey, also received grants to induce them to promote Aventis drugs. Relator learned from Mr. Ramharack that medical institutions knew Aventis provided such purportedly "educational" grants to encourage sales of its prescription drugs.

89. In addition, Aventis uses several methods to promote off-label uses for its drugs through the vehicle of kickbacks. First, Aventis provides its sales representatives with thousands of dollars in unrestricted educational grants to pay doctors to promote the benefits of off-label

use. According to Mr. Campbell, Aventis directly provides such grants to doctors to reward the largest purchasers of Taxotere.

90. For example, Mr. Campbell explained that Aventis provided Dr. Paula Kline of St. Vincent's Hospital in New York, N.Y. with a $3,500 direct grant to speak to doctors at Union Hospital in Union, New Jersey about off-label uses for Taxotere. Mr. Campbell also revealed that similar grants were paid to doctors at Sloan Kettering Medical Center and Staten Island Hospital.

91. The Relator also learned that Aventis maintains lists of doctors using Aventis drugs for off-label purposes, and invites the leading off-label prescribers to conferences where such uses are actively promoted. The individuals at Aventis charged with the responsibility of keeping these lists and helping to organize these conferences are the POEMs detailed above. One such individual in the New Jersey and New York area is named Patti Merwin.

92. Mr. Campbell disclosed that Aventis typically invites seven to ten doctors to attend these conferences, and pays those who do attend between $750 to $1,000 in gifts as an inducement to promote Taxotere for off-label uses, and to themselves prescribe Taxotere for such use.

93. Upon information and belief, Aventis engaged on a nationwide basis in the illegal practice of paying speaker's fees or educational grants to induce doctors to prescribe its drugs. If officials at the government-funded health programs from whom reimbursement was sought for Aventis's drugs knew that the physicians and medical institutions seeking such reimbursement received illegal inducements from Aventis, they would not have made payment. Thus, on every occasion where a physician received a speaker's fee or an educational grant and later sought

reimbursement for Aventis drugs from federal government-funded health programs, a false or fraudulent claim was submitted.

94. On each occasion in which a physician or medical institution submitted such a false or fraudulent claim, Aventis knew or acted in reckless disregard of the fact that such a false or fraudulent claim would be submitted. By such conduct, Aventis caused the false or fraudulent claim to be submitted, and is itself liable for such false or fraudulent claims.

95. Upon information and belief, Aventis engaged – on a nationwide basis – in the illegal practice of unlawfully inducing physicians to promote off-label uses for its prescription drugs.

96. The grants and gifts Aventis provides to doctors in exchange for their prescriptions of Aventis drugs for off-label uses are illegal, both because they violate the FDCA as an illegal effort to promote an off-label use of Aventis drugs, and because they constitute kickbacks under the Medicare Anti-Kickback Statute.

97. On each occasion that a physician or medical institution submitted a claim to a government-funded health program seeking reimbursement for an off-label prescription for Aventis drugs, which Aventis illegally promoted by providing the physician or medical institution with an illegal gift or grant, Aventis caused a false or fraudulent claim to be submitted under the FCA.

98. On each occasion in which a physician or medical institution submitted such a false or fraudulent claim, Aventis knew or acted in reckless disregard of the fact that such a false or fraudulent claim would be submitted. By such conduct, Aventis caused the false or fraudulent or fraudulent claim to be submitted, and is itself liable for such false or fraudulent claims.

2. Kickbacks by Providing Free Drugs Billed to the Government

99. One of Aventis's most common – and effective – methods of providing kickbacks to doctors is to overfill a prescription or provide free samples of its drug products. The doctors or medical institutions receiving the surplus then bill the government for the medicine at average wholesale price or best price, so as to receive reimbursement as if they had paid for the free drugs, thereby keeping the full reimbursement as an illegal kickback from Aventis. Mr. Campbell stated that the magnitude of such overbilling might reach 20 to 30 percent or more per vial of medicine. Through this practice, Aventis helped doctors and medical institutions "get the most out of the vials" so as to maximize their "financial advantage."

100. Relator had several conversations with Rohan Ramharack, who served as a clinical oncology sales manager at Aventis for the New Jersey/Northeast region since 1997, in which Mr. Ramharack disclosed the Defendant's scheme to provide the doctors with free medicines.

101. As part of Mr. Ramharack's marketing effort, he routinely provided physicians with as many as 1,200 free samples a year. These samples, on average, had a market value of approximately $120,000, thereby giving Mr. Ramharack alone $120,000 a year in marketing "leverage" against his competitors. Mr. Ramharack revealed that all 116 sales representatives in Aventis's oncology market give away samples on this magnitude. Over a five-year period, such an effort amounted to over $50 million in illegal remuneration.

102. Mr. Ramharack also disclosed that Aventis provided physicians with overfilled prescriptions containing excess product which the physicians would use to treat other patients, resulting in the physicians' billing the government for an additional 100 or more vials per month. These additional drugs, like the free drug samples, could be billed by the physicians or medical institutions to a government-funded insurer for full reimbursement, all of which constitutes an

illegal kickback to the physicians. Thus, such overfilled prescriptions and free samples amount to a bribe calculated to induce the physicians to prescribe Aventis drugs.

103. Mr. Ramharack informed Relator that he provided Dr. Richard Burke, head of the formulary committee at Mount Sinai Hospital, with free samples of Anzemet for 15 to 20 patients. Aventis was aware that by billing Medicaid and Medicare for the free samples, Dr. Burke would collect at least $30,000 on the free samples.

104. In a typical situation, Aventis offered a Healthcare Formulary Group prescription drugs at prices discounted in proportion to the percentage of the market share in prescriptions the Group offered Aventis for its products. Aventis typically sought a market share from a given Healthcare Formulary in the range of 50 percent to as much as 90 percent.

105. Aventis's inducements of free samples and overfilled prescriptions, and specifically the illegal profit derived from them, induced Dr. Burke to promote Anzemet at the hospital's formulary committee. Dr. Burke's endorsement, in turn, brought Aventis $750,000 a year in sales from Mount Sinai.

106. Aventis engaged on a nationwide basis in the practice of providing physicians with free samples and/or overfilled prescriptions, to encourage physicians and medical institutions to seek reimbursement from the government for drugs for which they did not pay.

107. On every occasion in which a physician or medical institution submitted a false claim by billing for free medicine provided by Aventis, a false claim was submitted.

108. On every occasion in which a physician or medical institution submitted a false claim by billing for free medicine provided by Aventis, Aventis knew or acted in reckless disregard of the fact that a false claim would be submitted. By such conduct, Aventis caused a false claim to be submitted, and is itself liable for the false claim.

3. Kickbacks by Providing Free Services to Doctors

109. Through his conversation with Mr. Campbell, Relator discovered that Aventis provides illegal free services to doctors.

110. For example, Aventis operates and provides practice management consulting services, referred to as PACT Plus, to certain physicians prescribing Aventis drugs. Relator learned from Mr. Campbell that, in addition to consulting services such as reimbursement and billing assistance, PACT Plus's services include helping doctors receive prescription drugs both manufactured by Aventis and by other companies, and finding inexpensive or free drugs for the doctors' indigent patients.

111. The Relator also learned from Mr. Campbell that Aventis provides pharmacists to teach physicians how to mix Taxotere and Anzemet prescriptions to give the doctors a financial advantage by getting "the most out of the vials." The pharmacists instruct the physicians on how to capture the excess of the overfilled prescriptions so that they may use that excess on other patients and bill the government for the new prescriptions.

112. These extraordinarily valuable services provided by Aventis to Aventis-prescribing physicians constitute illegal kickbacks or inducements to encourage the physicians to prescribe Aventis drugs.

113. Upon information and belief, Aventis engaged, on a nationwide basis, in the practice of providing free consulting services to physicians in exchange for those physicians buying or promoting Aventis drugs.

114. On every occasion in which a physician or medical institution received free services from Aventis, and later sought reimbursement for Aventis drugs from federal government-funded health programs, false claims were submitted.

115. On every occasion in which a physician or medical institution received free services from Aventis, and later sought reimbursement for Aventis drugs from government health programs, Aventis knew, or acted in reckless disregard, that a false claim was being submitted, and therefore caused that false claim to be submitted, and is itself liable for such false claim.

D. Aventis's Violations of the Medicaid Rebate Statute

116. By paying illegal kickbacks and offering price discounts to physicians which are not disclosed to the government in violation of the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, Aventis caused and/or induced physicians and medical institutions seeking reimbursement for Aventis drugs from federal government-funded health programs to file false or fraudulent certifications in violation of the FCA and the state false claims acts.

117. Aventis provides free prescription drug samples and overfills prescriptions in copious amounts which could be billed by physicians or medical institutions to government-funded payors for full reimbursement. Aventis also provides prescribing physicians with pharmacists to teach them how to mix Taxotere and Anzemet prescriptions to provide doctors with a financial advantage by getting "the most out of the vials." Through this practice, Aventis provides illegal rebates to prescribing physicians.

118. On information and belief, Aventis engaged on a nationwide basis in the practice of providing physicians and medical institutions with free samples and/or overfilled prescriptions, to allow those physicians and medical institutions to seek reimbursement from the government for drugs for which they did not pay. On information and belief, the doctors or medical institutions receiving the bonus drugs then bill the Government for the medicines at "average wholesale price," or "best price," so as to receive reimbursement as if they paid for the free drugs, thereby keeping the full reimbursement as an illegal kickback.

119. Aventis provided Medicaid with "best price" information which excluded the additional cost of cash discounts and free goods, in the form of free samples, overfilled prescriptions, and free services calculated to maximize the product quantity, all of which Aventis illegally provided to physicians to induce them to prescribe Taxotere and Anzemet.

120. On information and belief, by intentionally concealing both the payment of kickbacks and price discounts to physicians and medical institutions, Aventis failed to accurately report the "best price" of Medicaid covered drugs as required by the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8. This resulted in millions of dollars of Medicaid overpayments to Aventis by both the federal and state governments.

121. On each occasion that Aventis provided "best price" information and Average Manufacturer Price information to CMS that excluded the costs of the free goods and services it provided to physicians and medical institutions, Aventis caused CMS to understate the amount of the rebate owed to the Medicaid Program. Aventis thereby caused a false claim to be submitted under the FDA.

E. Sanofi's Unlawful Kickback Scheme

122. Sanofi routinely pays kickbacks and other illegal remuneration to physicians to induce them to prescribe Sanofi drugs, including Plavix and Avapro, to increase Sanofi's prescription drug market share and ultimately its profits. The kickbacks Sanofi pays to prescribing physicians come in many forms, include cash payments, speaker's fees and other inducements.

123. Further, Sanofi targeted many kickbacks to those prominent physicians and other healthcare professionals whose stature enabled them to influence their institutions' drug purchasing decisions.

124. On every occasion in which a physician or medical institution received a kickback or price discount from Sanofi and later sought reimbursement for Sanofi drugs from federal government-funded health programs, a false claim was submitted in violation of the FCA.

125. On December 1, 2003, the Relator interviewed Orren Taylor, a marketing representative for Sanofi, covering the New York-New Jersey metropolitan area.

126. Mr. Taylor told the Relator that, as a matter of company policy, the sales representatives select the top-selling prescribers of Sanofi drugs. These doctors would be recommended to an FDL Therapeutic Liaison, who would arrange to have the doctor placed on speakers list for various drug symposia. Those symposia were ostensibly arranged and controlled by third-party vendors, Boron LePore & Associates and Cogenics, Inc.

127. Mr. Taylor disclosed that members of Sanofi's sales force would maintain "call lists" identifying approximately 165 high-prescribing physicians whom the Company would enlist to help promote Plavix and Avapro.

128. The doctors selected on the basis of their high sales were paid speakers fees between $1,000 and $2,000 for each engagement. The marketing representatives are given $36,000 a year in discretionary budgets to dole out as rewards to physicians, all of it based on sales data.

129. Similarly, Sanofi pays "speaker's fees" to physicians to attend lectures, and provides lavish dinners and cash payments. These benefits are intended to reward physicians for prescribing Sanofi drugs, and to induce them to prescribe more Sanofi drugs in the future. Additionally, Sanofi provides $100 "educational grants" to physicians to attend these events and induce them to purchase Sanofi drugs. Mr. Taylor also disclosed that Sanofi would "bend the rules or choose a cheaper price" for the dinner events, so that the Company would be able to

"ease the money backdoor" should they want to make direct payments to the speakers, which Sanofi would characterize as "honoraria." The physicians accept these fees without any formal obligation on their part to provide consulting or other services in return.

130. About one-third of the doctors on Mr. Taylor's list of contacts sold Sanofi products because of these inducements.

131. For example, Sanofi rewarded Michael Schloss, a cardiologist at New York University Medical Center, for prescribing large sales of Avapro.

132. Similarly, Sanofi paid one high-volume prescriber of Plavix, Dr. Allen Unger, of the Mount Sinai Hospital, between $1,000 and $2,500 to invite his colleagues, including cardiologist Jose Meller, to lavish dinners at which Mr. Unger would discuss Plavix using "promotional materials" provided to him by "medical liaisons" hired by Sanofi.

133. The Medical Liaison, Isabella Batsue, oversees Sanofi's marketing efforts from New Jersey to Boston.

134. On each occasion in which a physician or medical institution submitted such a false or fraudulent claim, Sanofi knew or acted in reckless disregard of the fact that such a false or fraudulent claim would be submitted. By such conduct, Sanofi caused the false or fraudulent claim to be submitted, and is itself liable for such false or fraudulent claims.

135. Upon information and belief, Sanofi engaged – on a nationwide basis – in the illegal practice of unlawfully inducing physicians to promote off-label uses for its prescription drugs.

136. The grants and gifts Sanofi provides to doctors in exchange for their prescriptions of Sanofi drugs for off-label uses are illegal, both because they violate the FDCA as an illegal

effort to promote an off-label use of Sanofi drugs, and because they constitute kickbacks under the Medicare Anti-Kickback Statute.

137. On each occasion that a physician or medical institution submitted a claim to a government-funded health program seeking reimbursement for an off-label prescription for Sanofi drugs, which Sanofi illegally promoted by providing the physician or medical institution with an illegal gift or grant, Sanofi caused a false or fraudulent claim to be submitted under the FCA.

138. On each occasion in which a physician or medical institution submitted such a false or fraudulent claim, Sanofi knew or acted in reckless disregard of the fact that such a false or fraudulent claim would be submitted. By such conduct, Sanofi caused the false or fraudulent or fraudulent claim to be submitted, and is itself liable for such false or fraudulent claims.

139. By paying illegal kickbacks and offering price discounts to physicians which are not disclosed to the government in violation of 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute), Sanofi has caused and/or induced physicians and medical institutions which sought reimbursement for Sanofi drugs from federal government-funded health programs to file false or fraudulent certifications regarding compliance with the foregoing statutes in violation of the FCA and the state false claims acts.

140. By paying illegal kickbacks which are not disclosed to the government in violation of the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, Sanofi caused and/or induced physicians and medical institutions seeking reimbursement for Sanofi drugs from federal government-funded health programs to file false or fraudulent certifications in violation of the FCA and the state false claims acts.

V. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

141. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 140 of this Complaint as if fully set forth herein.

142. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein Defendant has knowingly presented or caused to be presented to officers or employees of the United States government false or fraudulent claims for payment or approval or failure to provide the Best Price for drugs in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(2))

143. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 142 of this Complaint as if fully set forth herein.

144. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendant has knowingly made, used, or caused to be made or used false records or statements – i.e., the false certifications and representations made or caused to be made by defendants, to get false or fraudulent claims paid or approved by the government in violation of 31 U.S.C. § 3729(a)(2).

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False Record
Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(7))

145. Relator repeats and incorporates by reference the allegations contained in

Paragraphs 1 through 144 of this Complaint as if fully set forth herein.

146. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants knowingly made, used or caused to be made or used false records or false statements—*i.e.*, the false certifications made or caused to be made by defendants—to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States.

FOURTH CAUSE OF ACTION

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(3)

147. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 146 of this Complaint as if full set forth herein.

148. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendant conspired to get false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims by the United States.

FIFTH CAUSE OF ACTION

(California False Claims Act)
(Cal. Govt. Code §§ 12651 *et seq.*)

149. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

150. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

151. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

152. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

153. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

154. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SIXTH CAUSE OF ACTION
(Delaware False Claims and Reporting Act)
(Del Code Ann. tit. 6, §§ 1201 *et seq.*)

155. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

156. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

157. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

158. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

159. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

160. Pursuant to Del Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTH CAUSE OF ACTION
(Florida False Claims Act)
(Fla. Stat. Ann. §§ 68.081 *et seq.*)

161. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

162. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

163. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

164. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid

and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

165. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

166. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTH CAUSE OF ACTION
(Georgia False Medicaid Claims Act)
(Ga. Code. Ann. §§ 49-4-168.1 *et seq.*)

167. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

168. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

169. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

170. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

171. By reason of the Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

172. Pursuant to Ga. Code. Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINTH CAUSE OF ACTION
(Hawaii False Claims Act)
(Haw. Rev. Stat. §§ 661-21 *et seq.*)

173. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

174. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

175. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

176. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

177. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

178. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TENTH CAUSE OF ACTION
(Illinois Whistleblower Reward and Protection Act)
(740 Ill. Comp. Stat. §§ 175/1 *et seq.*)

179. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint.

180. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

181. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

182. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

183. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

184. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every

false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

ELEVENTH CAUSE OF ACTION
(Indiana False Claims and Whistleblower Protection Act)
(Ind. Code §§ 5-11-5.5-1 *et seq.*)

185. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint.

186. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

187. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

188. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

189. By reason of the Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

190. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWELFTH CAUSE OF ACTION
(Louisiana Medical Assistance Programs Integrity Law)
(La. Rev. Stat. Ann. §§ 46:439.1 *et seq.*)

191. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

192. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

193. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

194. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

195. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

196. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTEENTH CAUSE OF ACTION
(Massachusetts False Claims Law)
(Mass. Gen. Laws ch. 12, §§ 5A *et seq.*)

197. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

198. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

199. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

200. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

201. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

202. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FOURTEENTH CAUSE OF ACTION
(Michigan Medicaid False Claims Act)
(Mich. Comp. Laws §§ 400.601 *et seq.*)

203. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

204. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

205. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

206. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

207. By reason of the Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

208. Pursuant to Mich. Stat. § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud plus triple the amount of damages suffered by the state as a result of the conduct by the person.

FIFTEENTH CAUSE OF ACTION
(Nevada False Claims Act)
(Nev. Rev. Stat. §§ 357.010 *et seq.*)

209. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

210. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

211. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

212. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

213. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

214. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SIXTEENTH CAUSE OF ACTION
(New Hampshire False Claims Act)
(N.H. Rev. Stat. Ann. § 167:61-b)

215. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

216. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

217. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

218. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

219. By reason of the Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

220. Pursuant to § 167:61-b, the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTEENTH CAUSE OF ACTION
(New Jersey False Claims Act)
(N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*)

221. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

222. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

223. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

224. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

225. By reason of the Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

226. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTEENTH CAUSE OF ACTION
(New Mexico Fraud Against Tax Payers Act)
(N.M. Stat. Ann. §§ 44-9-1 *et seq.*)

227. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

228. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

229. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

230. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

231. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

232. Pursuant to N.M. Stat. Ann. § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINETEENTH CAUSE OF ACTION
(New York False Claims Act)
(N.Y. State Fin. Law §§ 187 *et seq.*)

233. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

234. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

235. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

236. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

237. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

238. Pursuant to N.Y. State Fin. Law § 189, the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTIETH CAUSE OF ACTION
(Oklahoma Medicaid False Claims Act)
(63 Okla. St. Ann. §§ 5053 *et seq.*)

239. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

240. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

241. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

242. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

243. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

244. Pursuant to 63 Okl. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY FIRST CAUSE OF ACTION
(The State False Claims Act (Rhode Island))
(R.I. Gen. Laws §§ 9-1.1-1 *et seq.*)

245. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

246. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

247. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

248. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

249. By reason of the Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

250. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every

false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY SECOND CAUSE OF ACTION
(Tennessee Medicaid False Claims Act)
(Tenn. Code Ann. §§ 71-5-181 *et seq.*)

251. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

252. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

253. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

254. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

255. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

256. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY THIRD CAUSE OF ACTION
(Texas Medicaid Fraud Prevention Law)
(Tex. Hum. Res. Code Ann. § 36.002)

257. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

258. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

259. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

260. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

261. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

262. Pursuant to Tex. Hum. Res. Code Ann. § 36.002, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY FOURTH CAUSE OF ACTION
(Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. §§ 8.01-216.1 *et seq.*)

263. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

264. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia Commonwealth Government for payment or approval.

265. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia Commonwealth Government to approve and pay such false and fraudulent claims.

266. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

267. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

268. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY FIFTH CAUSE OF ACTION
(Wisconsin False Claims for Medical Assistance Law)
(Wisc. Stat. § 20.931)

269. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint as if fully set forth herein.

270. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

271. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

272. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

273. By reason of the Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

274. Pursuant to Wisc. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY SIXTH CAUSE OF ACTION
(District of Columbia False Claims Act)
(D.C. Code Ann. §§ 2-308.03 *et seq.*)

275. Relator repeats and incorporates by reference the allegations contained in paragraphs 1 through 148 of this Complaint.

276. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

277. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

278. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

279. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

280. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

WHEREFORE, Relator Joseph Piacentile requests that judgment be entered against the Defendants, ordering that:

a. The Defendants cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and the state false claims acts;

b. The Defendants each pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of the Defendants' actions, plus the appropriate amount to the Certain States under similar provisions of the state false claims acts;

c. Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;

d. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;

e. The Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

f. The Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

g. The United States, the Certain States, and Relator Joseph Piacentile recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator Joseph Piacentile hereby demands a trial by jury.

Dated: September 4, 2009

STONE & MAGNANINI LLP

By: _____

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